K101242

510(k) Summary for Honeywell HomMed Genesis DM Monitor

JUN 11 2010

Submitter:	Honeywell HomMed, LLC
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Corporate Contact:	Emily Vande Hei, Regulatory Manager and Quality Champion Honeywell HomMed, LLC
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Establishment Registration #:	3004183721
Submission Contact:	Emily Vande Hei, Regulatory Manager and Quality Champion Honeywell HomMed, LLC 3400 Intertech Drive, Suite 200 Brookfield, Wisconsin 53045 Ph: (262) 252-6082 Fax: (262) 252-6119
Trade Name:	Genesis DM Monitor
Predicate Device:	HomMed Genesis OTC, K061087 Omron Automatic Blood Pressure Monitor Model:HEM-780N3, K061822
Common Name:	Patient Vital Signs Monitor

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
870.2910	DRG	Radiofrequency Physiological Signal Transmitter and Receiver	II
Medical device product codes also supported by Genesis DM by means of separate medical devices			
870.1130	DXN	Noninvasive Blood Pressure Measurement System	II
880.2700	FRI	Patient Weight Scale	I
870.2700	DQA	Oximeter	II
862.1345	NBW	Glucose Test System	II
868.1860	BZH	Meter, Peak Flow, Spirometry	II
880.2910	FLL	Thermometer, Electronic, Clinical	II
864.7750	GJS	Test, Time, Prothrombin	II
870-2340	DPS	Electrocardiograph	II
890.5060	NXB	Medication Reminder	I

Intended Use:

The Honeywell HomMed Genesis DM Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, and weight. Data from optional

commercial stand-alone products extend Genesis DM Monitor's measurement capabilities. Data from the Genesis DM Monitor can be transmitted via a communication module to a central viewing station for display. The Genesis DM Monitor is not intended for emergency use or real-time monitoring.

Performance Data:

Completed EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity testing demonstrate compliance with applicable standards. The software validation results demonstrated that the Genesis DM Monitor was in compliance with the guidelines and standards referenced in the FDA reviewer's guides, and that it performed within its specifications and functional requirements for software.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of FDA regarding medical device software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Honeywell HomMed
c/o Ms. Emily Vande Hei
Regulatory Manager and Quality Champion
3400 Intertech Drive, Suite 200
Brookfield, WI 53045

JUN 11 2010

Re: K101242
Trade/Device Name: Genesis DM, Model 6053000A1
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitter and receiver
Regulatory Class: II (two)
Product Code: DRG
Dated: June 1, 2010
Received: June 3, 2010

Dear Ms. Vande Hei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

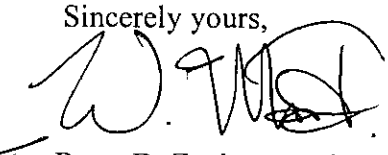
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101242

Device Name: Honeywell HomMed Genesis DM

Indications For Use:

The Honeywell HomMed Genesis DM Monitor is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse rate, and weight. Data from optional commercial stand-alone products extend Genesis DM Monitor's measurement capabilities. Data from the Genesis DM Monitor can be transmitted via a communication module to a central viewing station for display. The Genesis DM Monitor is not intended for emergency use or real-time monitoring.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101242